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09/988,013	11/16/2001	Shui-on Leung	IMMU:014US2	7681

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EXAMINER	
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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHUI-ON LEUNG and HANS HANSEN

Appeal 2008-6211
Application 09/988,013
Technology Center 1600

Decided[1]: March 13, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and
LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 28, 29, 31, and 32, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

The claims are directed to a method of designing amino acid sequences of variable domains of a humanized monoclonal antibody. Claim 28 is illustrative:

28. A method of designing amino acid sequences of variable domains of a humanized monoclonal antibody comprising:

(a) comparing the amino acid sequences of the light and heavy chain variable domains of a monoclonal antibody to be humanized with the amino acid sequences of the light and heavy chain variable domains of two or more human antibodies;

(b) selecting framework regions from a first human antibody for the light chain and from second and third human antibodies for the heavy chain based on the sequence comparison, wherein the heavy chain FR1, FR2 and FR3 are selected from the second human antibody and FR4 is selected from the third human antibody; and

(c) incorporating the framework regions selected in step (b) with the corresponding light and heavy chain complementarity determining regions of the monoclonal antibody to be humanized, to design humanized light and heavy chain variable domain amino acid sequences

wherein the heavy chain FR4 is selected from the human NEWM antibody, the light chain framework regions are selected from the human REI antibody, and the heavy chain FR1, FR2 and FR3 are selected from the human EU antibody.

The Examiner relies on the evidence:

Leung et al. (Leung I)	US 5,789,554	Aug. 4, 1998

Scott D. Gorman, *Reshaping a therapeutic CD4 antibody,* 88 Proc. Natl. Acad. Sci. USA 4181-4183 (1991).

S.O. Leung (Leung II), *Chimerization of LL2, a Rapidly Internalizing Antibody Specific for B Cell Lymphoma*, 13 Hybridoma 469-476 (1994).

The rejections as presented by the Examiner are as follows:

1. Claims 28, 29, 31, and 32 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

2. Claims 28, 29, 31, and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Leung I.

3. Claims 28, 29, 31, and 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Leung II.

We reverse.

Written Description:

ISSUE

Has the Examiner met his burden of establishing that Appellants' Specification lacks written descriptive support for the claimed invention?

PRINCIPLES OF LAW

> "The 'written description' requirement . . . serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. . . . The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence."

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). *See also* Falko-Gunter *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) ("[E]xamples are not necessary to support the adequacy of a written description[;] . . . the written description standard may be met . . . even when actual reduction to practice of an invention is absent.").

FINDINGS OF FACT

FF 1. The Examiner finds that Appellants "claims are drawn to a method of designing and producing a subgenus of humanized antibodies that comprise just any CDRs, *or* comprising the heavy chain FR4 sequence of the human NEWM antibody, *or* comprising the light chain frameworks of human REI, *or* comprising the heavy chain FR1, FR2 and FR3 from the human EU antibody" (Ans. 3 (emphasis added)).

FF 2. The Examiner finds that "there are insufficient published reshaping results to generalize a 'best framework' selection strategy (Gorman et al, at pg. 4182, 2nd col.)" (Ans. 4).

FF 3. The Examiner finds that "[t]here is no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other CDRs other than the LL2 are suitable for grafting onto the human REI light chain frameworks and onto the human Eu and NEWM heavy chain frameworks" (*id.*).

FF 4. The Examiner finds that "applicants' priority documents only provide adequate written support for the humanization of murine monoclonal antibody LL2 wherein the light chain frameworks are from the human REI antibody and the heavy chain frameworks for FR1-FR3 are from the human EU antibody and heavy chain FR4 is from the human NEWM antibody" (Ans. 5).

ANALYSIS

We disagree with the Examiner's finding that Appellants "claims are drawn to a method of designing amino acid sequences of variable domains of a humanized monoclonal antibody comprising "the heavy chain FR4

sequence of the human NEWM antibody, *or* comprising the light chain frameworks of human REI, *or* comprising the heavy chain FR1, FR2 and FR3 from the human EU antibody" (FF 1). Claim 28 requires that the "the heavy chain FR4 is selected from the human NEWM antibody, the light chain framework regions are selected from the human REI antibody, and the heavy chain FR1, FR2 and FR3 are selected from the human EU antibody" (Claim 28 (emphasis added)). Claims 29, 31, and 32 depend directly or indirectly from claim 28.

The Examiner admits that "applicants' priority documents . . . provide adequate written support for the humanization of murine monoclonal antibody LL2 wherein the light chain frameworks are from the human REI antibody *and* the heavy chain frameworks for FR1-FR3 are from the human EU antibody *and* heavy chain FR4 is from the human NEWM antibody" (FF 4). The instant application is a continuation of Appellants' priority documents (*see e.g.*, App. Br. 5-6). Therefore, the present Specification shares the same Specification as Appellants' priority documents. By concluding that the priority documents provide adequate written descriptive support for the claimed invention the Examiner has conceded that the present Specification has adequate written descriptive support for the claimed invention.

As Appellants point out, the LL2 monoclonal antibody was used in the Specification to exemplify the claimed method, not to limit the scope of the claimed invention. We agree. Further, we are not persuaded by the Examiner's reliance on Gorman's teaching that "there are insufficient published reshaping results to generalize a 'best framework' selection strategy" (FF 2). There is no requirement in the claimed invention that the

"best framework" regions be used, or that the resulting humanized antibody will have the same binding affinity as the underlying monoclonal antibody. Thus, the Examiner's reliance on Gorman appears to be misplaced not only because the claims do not require a "best framework" selection, but also because the Examiner's argument appears to be directed to an issue of enablement, not written description.

CONCLUSION OF LAW

The Examiner failed to meet his burden of establishing that Appellants' Specification lacks written descriptive support for the claimed invention. The rejection of claims 28, 29, 31, and 32 under the written description provision of 35 U.S.C. § 112, first paragraph is reversed.

Anticipation:

ISSUE

Did the Examiner establish that claims 28, 29, 31, and 32 fail to receive the benefit of Appellants claim of priority to U.S. Application No. 08/289,576, filed August 12, 1994?

FINDINGS OF FACT

FF 5. The Examiner finds that "the disclosure of the prior-filed application, USSN 08/820,576 . . . does not provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for the present claims (see item nos. (9)(a) and (10)(a) above)." (Ans. 14.)

PRINCIPLES OF LAW

35 U.S.C. §120 states:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States . . ., which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 102(b) states:

> A person shall be entitled to a patent unless —
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

ANALYSIS

For the reasons set forth above, we disagree with the Examiner's conclusion that Appellants' Specification lacks adequate written descriptive support for the claimed invention. Further, we recognize the Examiner's reference to Application No. 08/820,576 (FF 5). Appellants do not claim benefit to Application No. 08/820,576. Instead, Appellants' priority claim reads as follows:

> This application claims benefit of priority to U.S. Serial No. 09/741,843 filed on December 22, 2000, which claims benefit of priority to U.S. Serial No. 09/127,902 filed on

> August 3, 1999, now U.S. Patent No. 6,187,287, which claims benefit of priority to U.S. Serial No. 08/690,102 filed on July 31, 1996, now U.S. Patent No. 5,789,554, which claims benefit of priority to U.S. Serial No. 08/289,576 filed on August 12, 1994, now abandoned.

(Spec. 1: ¶ 0001 (emphasis added).)

As Appellants explain, the present application is a direct continuation of U.S. Application No. 08/289,576 (App. Br. 14). Thus, the present Specification is the same as the Specification in U.S. Application No. 08/289,576.

Accordingly, since Leung I and/or Leung II were not patented or published, respectively, more than one year prior to the August 12, 1994 filing date of Appellants' U.S. Application No. 08/289,576 they do not meet the requirements of 35 U.S.C. § 102(b).

CONCLUSION OF LAW

The Examiner failed to establish that claims 28, 29, 31, and 32 fail to receive the benefit of Appellants claim of priority to U.S. Application No. 08/289,576, filed August 12, 1994.

The rejection of claims 28, 29, 31, and 32 under 35 U.S.C. § 102(b) as being anticipated by Leung I is reversed.

The rejection of claims 28, 29, 31, and 32 under 35 U.S.C. § 102(b) as being anticipated by Leung II is reversed.

REVERSED

Ssc:

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